

R E M A R K S

Applicant herein respond to the final office action mailed September 23, 2002. Applicant have made minor amendments to the claims and have added claims 82-90. Support for the added claims can be found in the specification at the top of pages 6 and 12. Upon entry of this amendment, claims 43-49, 51-62, 73, and 75-90 will be pending. Applicants appreciate the withdrawal of several rejections and objections.

The claimed invention is not taught by Chandra

On pages 3-4-7 of the office action, the examiner rejected claims 43-49, 51-62, 55-62, 73 and 75-81 as anticipated by the Chandra patent. Applicant respectfully traverses these rejections.

Applicant notes that in order to reject a claim under 35 USC § 102, the examiner must demonstrate that each and every claim term is contained in a single prior art reference. See *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986); see also MPEP § 2131 (August 2001). Claim terms are to be given their plain meaning as understood by the person of ordinary skill in the art, particularly given the limitations of the English language. See MPEP §§ 707.07(g); 2111.01 (August 2001). Claims are to be given their broadest reasonable interpretation consistent with Applicant's specification. See *In re Zletz*, 13 USPQ2d 1320, 1322 (Fed Cir. 1989) (holding that claims must be interpreted as broadly as their terms ***reasonably*** allow); MPEP § 2111 (August 2001).

Not only must the claim terms, as reasonably interpreted, be present, an allegedly anticipatory reference must enable the person of ordinary skill to practice the invention as claimed. Otherwise, the invention cannot be said to have been already within the public's possession, which is required for anticipation. See *Akzo, N.V. v. U.S.I.T.C.*, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986); *In re Brown*, 141 USPQ 245, 249 (CCPA 1964).

As explained in its abstract, the Chandra patent discloses adsorbing Factor IX to a solid phase and then treating it with just a detergent solution. Also, the examiner admits in the obviousness rejection discussed below that Chandra does not disclose a chaotropic agent, which is recited in claims 53 and 54. In contrast, the claimed invention, as clarified herein, incubates the biological material in the presence of the alkyl phosphate-free detergent solution that contains at least one eluotropic salt (which can be a chaotropic agent) in a total eluotropic salt concentration of at least 200 mM (0.2M). Applicant's invention provides an elegant approach that effectively inactivates microorganism and pyrogens while preserving protein(s) contained in the biological material, which is economical and readily practiced at an industrial scale. See applicant's specification at page 3. Accordingly, Chandra does not teach these and other aspects of present invention, and therefore the rejection should be withdrawn.

***The claimed invention is not suggested by the combination of
Chandra, Hrinda and Eibl***

On pages 5-6 of the office action, the examiner for the first time rejected claims 43-49, 51-62, 73 and 75-81 as obvious over Chandra in view of Hrinda and Eibl.

Chandra was applied as before, although the examiner admitted that Chandra did not teach a chaotropic agent (which was not mentioned in the above-discussed anticipation rejection).

At the outset, applicant notes that the examiner must show all of the recited claim elements in the combination of references that make up the rejection. When combining references to make out a *prima facie* case of obviousness, the examiner is obliged to show by citation to specific evidence in the cited references that (i) there was a suggestion/motivation to make the combination and (ii) there was a reasonable expectation that the combination would succeed. Both the suggestion/motivation and reasonable expectation must be found within the prior art, and not be gleaned from applicants' disclosure. *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988); *W.L. Gore v. Garlock, Inc.*, 220 USPQ 303, 312-13 (Fed. Cir. 1983) (holding that is improper in combining references to hold against the inventor what is taught in the inventor's application); see also MPEP §§ 2142-43 (August 2001). Thus, the examiner must provide evidentiary support based upon the contents of the prior art to support all facets of the rejection, rather than just setting forth conclusory statements, subjective beliefs or unknown authority. See *In re Lee*, 277 F.3d 1338, 1343-44 (Fed. Cir. 2002).

When an examiner alleges a *prima facie* case of obviousness, such an allegation can be overcome by showing that (i) there are elements not contained in the references or within the general skill in the art, (ii) the combination is improper (for example, there is a teaching away or no reasonable expectation of success) and/or (iii) objective indicia of patentability exist (for example, unexpected results). See *U.S. v. Adams*, 383 U.S.

39, 51-52 (1966); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d 1923, 1927 (Fed. Cir. 1990); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 230 USPQ 416, 419-20 (Fed. Cir. 1986).

Applicant submits that the examiner has not established a suggestion in the references to combine them in the manner attempted by the examiner. Rather, the rejection evinces a proscribed hindsight reconstruction of the prior art. Accordingly, applicants submit that the examiner has not established a *prima facie* case of obviousness, and therefore the rejection should be withdrawn.

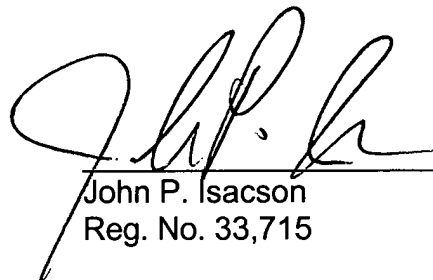
Request

Applicant submits that the claims are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 912-2000 should there be any questions.

Respectfully submitted,

October 23, 2003

Date



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